UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,242	07/02/2003	Yvo Maria Franciscus Graus	05032-00031	3317

22910 7590 01/12/2007

BANNER & WITCOFF, LTD.
28 STATE STREET
28th FLOOR
BOSTON, MA 02109-9601

EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,242	GRAUS ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,27,28,30-47 and 60-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,27,28,30-47 and 60-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 02 November 2006 is acknowledged and has been entered. Claims 24, 27, 28, 30-47, and 60-62 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly presented claim 60 is rendered vague and indefinite by the phrase "A food product or drink ...wherein the daily dose of chlorogenic acid and functional analogs thereof is 0.5-500 mg, and the daily dose of zinc is 1-200 mg" for the following reasons. The latter part of this phrase is apparently attempting to define the instantly claimed food product or drink in terms of (intended) daily dosage amounts which is unclear and confusing since a food or drink is not a form by which a dosage amount properly reads upon. For example, if you take a swallow of a drink or a bite of a food product (containing the recited ingredients), are these intended to define a daily dosage amount (or is the daily dosage amount intending to define an entire drink or multiple drinks consumed daily, and/or a whole food or multiple food items consumed daily) and, if so, what is the overall volume/quantity of drink or food with respect to correlating such a daily dosage amount? For these reasons, the daily dosage amount ranges instantly claimed for chlorogenic acid and zinc in claim 60 are essentially meaningless with respect to defining an actual amount range for each these ingredients within the instantly claimed food product or drink.

New claim 61 is rendered vague and indefinite for the same reasoning set forth immediately above for claim 60.

Claim Rejections - 35 USC § 102

Claims 24, 28, 30, 31, 32, 37-43, 45, 48, and 60-62 stand/are rejected under 35 U.S.C. 102(b) as being anticipated by Coudray et al. (Br. J. Nutrition, 1998) with evidence provided by Klemann et al. (US 5,906,852)*.

A food or drink preparation comprising chlorogenic acid and zinc (within expansive ratio ranges) is claimed. Dependent claims include the preparation further comprising a component such as polysaccharides, trace elements, and/or vitamins.

Coudray et al. teach a dietary food (meal) preparation comprising chlorogenic acid to which zinc is also added. The reference ratio range of chlorogenic acid to zinc is within the expansive ratio ranges instantly claimed. The reference meal preparation further comprises polysaccharides (including in the form of cellulose), other trace elements such as copper, and vitamins. Please note, as evidenced by Klemann et al., cellulose is a polysaccharide composed of 1,4-linked glucose units which is a ubiquitous fiber found in all plant sources including fungi (see, e.g., col 1, lines 24-27). Accordingly, the cellulose taught by Coudray et al. inherently reads upon a polysaccharide isolated from fungi (as instantly claimed). This reference further teaches that the polyphenol meal preparation (containing the polyphenol chlorogenic acid) is prepared as a semi-liquid food (thus, reads upon a solution, liquid, gel, and/or suspension). See, e.g., page 576 under the headings *Animals and diet* and *Polyphenol study: acute effect of polyphenol ingestion on zinc and copper absorption*. Please also note that the daily dose mg

limitations recited in claims 60 and 63 are not deemed to lend patentable weight to the claimed food product or drink recited therein (based upon the USC 112, 2nd paragraph rejection above).

Therefore, the reference is deemed to anticipate the instant claims above.

* Please note that the Klemann et al. (US 5,906,852) reference is not being cited as art within the USC 102 rejection above, but rather to show the inherent properties of cellulose, as discussed within the USC 102 rejection above.

Claim Rejections - 35 USC § 103

Claims 24, 28, 30, 31, 32, 37-45, 47, and 48 stand/are rejected under 35 U.S.C. 103(a) as being unpatentable over Coudray et al. (Br. J. Nutrition, 1998) in view of Klemann et al. (US 5,906,852).

The Coudray et al. reference is relied upon for the reasons set forth above. Coudray et al. do not expressly teach that the cellulose (polysaccharide) within their food meal preparation is obtainable from fungi (although, as noted above, cellulose inherently defines a particular polysaccharide having 1,4-linked glucose units which is indistinguishable no matter its source and, thus, its source is not deemed a distinguishing characteristic). Again, please also note that the daily dose mg limitations recited in claims 60 and 63 are not deemed to lend patentable weight to the claimed food product or drink recited therein (based upon the USC 112, 2nd paragraph rejection above).

Klemann et al. beneficially discloses that cellulose is a ubiquitous fiber found in all plant materials including fungi (see, e.g., col 1, lines 24-27).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize cellulose obtained from fungi within the food meal preparation

taught by Coudray et al. based upon the beneficial teaching provided by Klemann et al. with respect to fungi being a well known, suitable source thereof. Further, although not expressly taught, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made include vitamin A and/or vitamin E within the vitamin mixture disclosed by Coudray et al: since both of these commonly-employed vitamins are notoriously well known in the art to be beneficially healthful when incorporated within a balanced vitamin-fortified meal/food. If not expressly taught, the adjustment of particular conventional working conditions (e.g., preparing such a meal formulation within a food bar, agglomerate, and/or drinkable solution) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the reference(s), especially in the absence of evidence to the contrary.

Claims 24, 27, 28, 30-47, and 60-62 stand/are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu (US 6,083,921), Squires (WO 98/11778), Carenzi et al. (US 5,080,906), and the admitted state of the art.

Xu beneficially teaches an anti-viral pharmaceutical composition comprising chlorogenic acid (including chlorogenic acid obtained from a plant) as an active immunomodulating agent therein. Xu further beneficially teaches such pharmaceutical compositions may be in the form of a tablet (which reasonably reads upon a food product) and that the tablet can include zinc stearate as a conventional ingredient therein (see entire document including abstract, col 3, lines 39-51, col 5, line 48-col 6, line 59; col 10, line 54 - col 11, line 15).

Squires beneficially teaches a pharmaceutical composition useful for treating viral infections including HIV comprising a functional analog of chlorogenic acid (such as 1,5-o-dicaffeoylquinic acid - among others - which is encompassed by 1,5-dicaffeoylquinic acid as well as by the chemical structure shown in claim 38). The reference also discloses that the composition comprises or my comprise polysaccharides, arabinogalactan, vitamin E (tocopherol), vitamin A (ascorbic acid), minerals, and plant extracts such as some of those instantly claimed (e.g., *Echinacea, Calendula* extr's)- see, e.g., pp 4-8, 10, 11, 14-16, and claims.

Carenzi et al. disclose that it is well known in the art to use N-acetyl cysteine in human therapy to beneficially stimulate immune systems debilitated by viral infections, including those debilitated by HIV (see, e.g., col 1, lines 11-21).

In addition, as readily admitted by Applicants (and/or as well recognized in the art), many of the instantly claimed additional ingredients are well known in the art to act as anti-viral and/or immunostimulant agents (see, e.g., pages 10-13 of the instant specification).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit (e.g., as antiviral agents) since each is well known in the art for the same purpose and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 U.S.P.Q. 1069 (CCPA 1980); In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426

(1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The adjustment of particular conventional working conditions (e.g., substituting zinc stearate for another equivalent zinc compound/zinc salt within an edible tablet formulation and/or determining an appropriate amount ratio of chlorogenic acid/analog to zinc compound/salt therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references (as well as the admitted state of the art), it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

With respect to art rejections above, please again note that each of the chlorogenic acid-zinc containing products taught or reasonably suggested by the cited references would intrinsically be capable of providing the intended functional effect(s) instantly claimed. In addition, the source from which the chlorogenic acid (as well as the source of cellulose used within the food meal preparation taught by Coudray et al. - as discussed *supra* and below) is obtained is not deemed to lend patentable distinction to the instantly claimed chlorogenic acid since chlorogenic acid is a defined chemical structure which would not vary regardless of from

which source it is obtained (e.g., whether it is obtained from a particular plant source or is synthetically made, it still is the same chemical compound with the same chemical structure and, thus, would not be distinguishable based upon such a source limitation).

Applicants' arguments as they pertain to the USC 102 and 103 rejections above have been carefully considered but are not deemed to be persuasive of error in the rejections.

Applicants argue that Coudray fails to teach a food product comprising at least one polysaccharide isolated from the recited species (including fungi). However, as discussed above (and as evidenced by Klemann et al.), cellulose is a polysaccharide composed of 1,4-linked glucose units which is a ubiquitous fiber found in all plant sources including fungi (see, e.g., col 1, lines 24-27). Accordingly, the cellulose taught by Coudray et al. inherently reads upon a polysaccharide isolated from fungi (as instantly claimed). Alternatively, if not inherent, it would clearly have been obvious to one of ordinary skill in the art to utilize cellulose isolated from fungi based upon the beneficial teachings provided by Klemann et al. with respect to fungi being a well known, suitable source thereof.

Applicants further argue that zinc stearate (as disclosed by Xu) is an organic zinc salt not an inorganic zinc salt nor is it zinc citrate. However, the active such a salt moiety is zinc which is inorganic. Further, as discussed above (without clear and convince evidence of criticality), the adjustment of this type of conventional working conditions (e.g., substituting zinc stearate for another equivalent zinc compound/zinc salt within a tablet formulation) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. In addition, with respect to the second USC 103 rejection above, Applicants have

argued and discussed references individually without clearly addressing the combined teachings (concerning the use of the instantly claimed ingredients within an anti-viral pharmaceutical composition, as reasonably disclosed by the cited references as a whole). It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher R. Tate
Primary Examiner
Art Unit 1655